endTB Clinical Trial
Research Screening Parental Consent Form

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Subject Identification

Protocol Title: endTB (Evaluating Newly approved Drugs for multidrug-resistant TB)

Sponsor: Médecins Sans Frontières (Doctors Without Borders) - France

Principal Investigators: Carole Mitnick, Sc.D. and Lorenzo Guglielmetti, M.D.

Site Principal Investigator: [Insert PI Name]

Research Center: [Insert Research Center Name]

Participant Name (please print): _____

Study Subject ID: _____

About this consent form

Your child has been diagnosed with multidrug-resistant tuberculosis (MDR-TB). We are conducting a study, called endTB, to see whether we can find a better treatment for MDR-TB. We would like to ask you whether you agree for your child to be interviewed and examined to see whether he/she could be in our study.

Please read this form, called research screening parental consent form, carefully. It tells you important information about evaluating your child for participation in a the endTB study. This evaluation is called "screening". A member of our research team will talk to you and your child about what it means to take part in the screening. People who agree to take part in screening are called "participants" in this consent form.

Introduction

TB is a disease caused by bacteria (or germ) that usually affects the lungs. It is passed from person to person through the air by droplets that come from the lungs of a person who is sick with TB. When the sick person coughs, sings, shouts or spits, the TB bacteria can make others sick. Most people with TB can be treated and cured, if they complete all their treatment. Some types of TB bacteria cannot be killed by the regular drugs (rifampicin and isoniazid). These bacteria are called multidrug resistant. People sick with multidrug resistant TB need different drugs for their treatment.

We are asking you to give permission for your child to be screened for the endTB study because he/she is less than 18 years of age (a minor), and has MDR-TB that is affecting his/her lungs. During this screening, we will do some laboratory tests and a doctor will examine your child to

see if he/she is eligible to be in the study. We will need both permissions from you (by signing this consent form) and your child (by signing an assent form) before having your child take part in this screening. Your child does not have to take part in this screening if either you or your child does not want to.

At least 2000 patients in 7 countries will be screened for this study. We expect about [number to be adapted locally] patients will be screened at [Research Center Name].

Médecins Sans Frontières (Doctors Without Borders) - France is the sponsor of this study.

If you have any questions about the screening or about this form, please ask us. Because your child is less than [18] years of age (a minor), we will need both permissions from you and your child before having your child screened for this screening. Taking part in the screening for this study is up to you and your child. Your child does not have to be screened if you or your child does not want to. Screening is the first step. If you agree to let your child be screened, we will ask that you sign this form to confirm that you accept your child to be screened for this study. We will give you a signed copy of this research screening parental consent form to keep. We will also give your child the same information and ask for his/her permission to screening. Your child will be free to refuse even after you give permission for him/her to be screened. His/her decision not to take part cannot be over-ridden by your decision. Your child can also decide to stop screening for this study at any time if he/she does not want to, even after you sign this form. Likewise, you can also decide not to let your child take part in this study at any time if you do not want to, even after signing this form.

If you are not able to sign the consent form, but you would like your child to take part in the research study, you can choose someone you know to sign for you and you can make a thumbprint to show that you understand the study and would like your child to be screened.

If you agree your child to be screened and he/she is eligible to be in the study, we will give you more information about the study and ask you to sign another form to show you agree your child to take part in the study.

Why is this study being done?

Current treatment for MDR-TB includes 5-9 drugs taken daily for 18 to 24 months. During at least six months, treatment includes a daily shot. This treatment may cause many mild and very serious side effects, for example: nausea, vomiting, hearing loss, numbness/tingling in fingers and toes, kidney damage, mental illness/feeling sad, etc. Two new drugs (delamanid and bedaquiline) have recently become available. New regimens containing one of these drugs may be shorter for example, 9 months and/or simpler (without injection). Such regimens have to be tested to see if they are safe and effective for people with multidrug-resistant TB. We are asking to screen your child for a study to test new 9-month-long, injection-free MDR-TB treatments. This research trial will compare new experimental treatment regimens to the current treatment for MDR-TB.

How long will the screening process take?

The complete screening process for this study could take 4 to 5 hours of your time. However, it is possible the doctors will need to see your child at separate visits to finish all the screening procedures. If that happens, all visits should be done within 2 weeks.

What will happen during screening?

We will ask you and your child to come to [Research Center Name]. We will ask you to sign this consent form before we do any screening procedures. Then, we will do some tests and procedures to see if your child is eligible to take part in the study. The study doctor will review the results of these tests and procedures. If your child cannot participate, the study doctor will tell you why and might ask you if your child will participate in another study.

Specifically, during screening, we will:

1. Answer all your questions and get your and your child's permission for screening.
2. Ask for your child's full name, contact information, sex, and age.
3. Review your child's medical history, including past or present illnesses, and information on drugs he/she is currently taking.

   The treatment your child will receive for TB may interact with some of the drugs that he/she is currently taking. The study doctor may review with you and your child if some of his/her drugs need to be stopped or changed prior to receiving any MDR-TB treatment.
4. Perform a complete check-up and ask about your child's TB symptoms.
5. Collect 2 tablespoons of your child's blood for laboratory testing to check if his/her body is functioning well.
6. Unless recent results are available, we will also ask to use the collected blood from your child for viruses that might affect your child's treatment for TB, like hepatitis B and C, which affect his/her liver and HIV, which affects his/her body's ability to fight infection.

   All test results will remain confidential. You and your child will have the right to decline these tests. Declining a test will not affect your child's participation to the study and the access to usual treatments that do not depend on knowledge of the test result. If the test result(s) is positive, your child will be referred to appropriate care. If your child has HIV infection, we will test his/her CD4 count and HIV viral load to see if the disease is well controlled.

7. Ask your child to cough up 3 sputum (or phlegm) samples. These will be used to test whether the TB bacteria can be treated with regular drugs and/or drugs in the study treatments. This is called testing for drug resistance.

8. Do a test, called an electrocardiogram, to check if your child's heart works normally.

9. Because we don't know if some of these medications are safe in pregnancy:

    - The study doctor will discuss birth control methods to avoid pregnancy (of your child or his/her partner) if your child is eligible and you and your child agree to his/her participation in the study.
    - Pregnant patients cannot enter the study. So, if your child is a girl who can get pregnant, we will collect a urine or blood sample for a pregnancy test. The study doctor will refer your child for TB treatment outside of the study if the test shows she is pregnant.

Depending on your child's test results:

- the study doctor may prescribe medications, for example to balance the level of salts in his/her blood, when possible;
- some of these tests may need to be repeated within the 2-week period; the study doctor will let you know which ones.

We will label all your child's samples and health information with a code instead of his/her name to keep all his/her information private. The key to the code connects your child's name to his/her samples and health information. The study doctor will keep the key to the code in a password protected computer and/or locked file.

Storing Isolates (strains) and Health Information for Future Research

We would like to store some of the bacteria isolates (TB bug) and your child's health information for future research related to TB, which will be collected during this screening. All your child's health information and bacteria isolates will be handled in a way to keep all his/her information private. Any use of stored bacteria isolates and your child's health information for other research inside your country or in other countries will be approved by the ethics committee of your country.

This future research is independent from being screened for the endTB study and your decision to let your child participate in the future research will not affect your child's participation in the screening for endTB study.

The bacteria isolates found in his/her sputum samples and his/her health information may be stored for up to 20 years in a special place (bank or repository) created to safely store them. The stored isolates and your child's health information will be used only to help future research in TB

and to improve diagnosis (including resistance testing) and treatment of TB. During your child's participation in the endTB study, and the following storage period of 20 years after completion of the study, you can contact the study doctor or the email address endTB.clinicaltrial@paris.msf.org to request any information regarding the use, storage and location of your child's health information and bacteria isolates.

Do you agree that your child's health information and the bacteria isolates found in his/her sputum samples may be stored for 20 years and used only for future TB research? You are free to refuse such storage and further use for TB research of your child's health information and bacteria isolates and your child can still take part in this screening.

☐ Yes ☐ No [Initials or signature, to be adapted locally]_____

You have the right to change your mind, and to later want your child's health information and/or bacteria isolates destroyed. In that case, during the participation of your child in the endTB study, and the following storage period of 20 years after completion of the study, you can contact the study doctor or the email address endTB.clinicaltrial@paris.msf.org to request any information regarding the use, storage and location of your child's health information and bacteria isolates and/or their destruction.

What are the risks and possible discomforts from being screened for this study?

Risks of Blood Draws

Your child may have a bruise (a black and blue mark) or pain where we take the blood samples. There is also a small risk of infection, light-headedness, and/or fainting.

What are the possible benefits from being screened for this study?

This screening evaluation has not been designed to give your child direct benefits but it may help your child to get treatment within the study, or get other appropriate treatment more quickly. Others with MDR-TB may benefit in the future from what we learn in this study**.**

Can my child still receive TB treatment if he/she does not take part in this screening?

Yes. Your child will receive treatment through [local TB care provider/entity] if he/she does not take part in this screening. Taking part in this screening is up to you and your child. You and your child can decide not to take part. There will be no penalty, and you and your child will not lose any benefits you receive now or have a right to receive.

What should I do if we want to stop taking part in this screening?

If you give your agreement for your child's screening and you change your mind, you should tell us.

Also, it is possible that we will have to ask your child to drop out of the screening before he/she finishes it. If this happens, we will tell you why.

And, we will tell you if we learn any new information that could make you change your mind and drop out later.

In any of these cases, we will discuss with you and your child and refer your child to other care, if needed.

Information collected during your child's screening will be used to help answer study questions. When your child leaves the study, his/her health information and information obtained from sputum samples and bacteria isolates previously collected may still be used and stored for 20 years for the study and future TB research. However, if you and your child prefer that this information is not used and that it is destroyed, you can contact your study doctor or the email address endTB.clinicaltrial@paris.msf.org.

Will we be paid to take part in this screening?

You or your child will not be paid to take part in this screening. However, we will cover transportation costs for visiting the research center(s). We will pay or you will be reimbursed [local currency] _____ for transportation to and from the screening visit.

What will we have to pay for if my child takes part in this screening?

All screening procedures will be free of charge to your child.

What happens if my child is injured as a result of taking part in this screening?

If your child suffers physical injury from the screening, _____ will give him/her immediate medical treatment.

_____ will not pay to treat a medical condition or disease your child had before screening or expenses for injury, treatment, or hospitalization your child may require that are not the result of your child's participation in the screening.

You do not waive any of your legal rights by signing this consent form.

Who can I speak to if I have questions, concerns or complaints?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want

[PI Name and title] is the person in charge of the screening and study. You can call him/her at [PI telephone number]. You can also call [Clinical Investigator] at [CI number] with questions. If you have questions about the scheduling of appointments or study visits, call [Study Coordinator] at [SC number].

If you want to speak with someone not directly involved in the screening or study , please contact the [Research Center IRB] office. You can call them at [Research Center IRB number].

If my child takes part in this screening, how will you protect our privacy?

We are careful to protect the identities of the people who are screened in this study to the extent permitted by law. We also keep your child's information secure and confidential. Electronic study information will be password-protected, and paper files will be stored in a locked office at [Research site]. Your child's screening records will be kept at the clinic/hospital for XX years [*to be adapted locally*] following the completion of the study. If needed to monitor the study quality, your child's screening information may be looked at by institutions responsible for quality and privacy such as the sponsor, Ethics Committee and Competent Authorities.

For the screening, we will store some non-medical information about your child, such as his/her date of birth and city of residence. You can ask us to access, modify, complete, update, or delete this information. If you have any complaints about the protection of your data, you could contact your local/national Data Protection Authority [*Name and contact to be adapted locally*].

The information collected for screening will be used for the following purposes:

- For the purposes of this study. The sponsor, the study doctor, or other doctors involved in the study may publish reports or articles on the screening or present screening findings to scientific groups. After the study is completed, you may see your child's records, and you may be told the results of the study.
- Secondary use for TB research; your coded information may be used and shared with other institutions only for the purpose of further TB research during and after completion of the study and notably with the World Health Organization.

In all cases your child's identity will never be disclosed.

Your child's coded information may be sent electronically to other researchers or institutions. If sent, it will be encrypted (scrambled so it cannot be read by people who shouldn't see it).
We guarantee that, when we send your coded information, it will be protected according to European Economic Area standards.

Subject Identification

Informed Assent and Authorization

Your signature on this document means the following:

I have read this parental consent form. The screening process has been explained to me, including risks and possible benefits, other possible treatments or procedures, and other important things about the study. I have had the opportunity to ask questions. I understand the information given to me. I recognize that my child's participation is voluntary and that I can refuse or end my child's participation at any time, without any loss of benefits that we would otherwise have.

I recognize that by signing this document, I do not lose any of my legal rights as parent/guardian of the participant. I will receive a complete, signed, dated copy of this research screening parental consent form.

By signing below, I give my permission to let my child take part in the screening.

Signature of Parent/Guardian of the Participant:

_____ _____

Signature or thumbprint of parent/guardian of the participant Date (DD/MMM/YYYY) and Time

_____

Name of parent/guardian of the participant, printed in capital letters

Witness (if applicable):

_____ _____

Signature of witness Date (DD/MMM/YYYY) and Time

_____

Name of witness, printed in capital letters

Subject Identification

Study representative who obtained informed assent:

I have explained this study to the parent/guardian of the participant and have answered all of his/her questions. He/she understands the information described in this document and accepts voluntary participation of his/her child in the study.

_____ _____

Signature of study representative Date (DD/MMM/YYYY) and Time

_____

Name of study representative, printed in capital letters